

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA,

v.

(1) STRYKER BIOTECH, LLC,

(2) MARK PHILIP,

(3) WILLIAM HEPPNER,

(4) DAVID ARD and

(5) JEFFREY WHITAKER,

Defendants.

Criminal No.: 09-CR-10330-GAO

**GOVERNMENT’S OPPOSITION TO DEFENDANTS’ MOTION IN LIMINE
TO EXCLUDE NEWLY IDENTIFIED GOVERNMENT WITNESSES**

The United States hereby opposes defendants’ motion to exclude testimony of witnesses who work for Institutional Review Boards (“IRBs”) at various Boston area hospitals that at one time used Stryker’s OP-1 medical device. These witnesses were interviewed by the government on December 21 and 22, 2011, and the reports of those interviews were disclosed to the defendants on December 27, 2011, once those interview reports were prepared.

The government’s witness list was due on January 2, 2012, and was timely filed and included some of the IRB witnesses who were interviewed recently. Defendants seem to have some theory that the government was obligated to disclose witnesses on some other unspecified schedule. They also seem to have a theory that all evidence that is presented at trial must also have been presented to the grand jury. Neither theory draws any support from law or practice.

The Superseding Indictment charges a number of crimes, including a conspiracy to defraud the FDA and to commit wire fraud. The “manner and means” section of the conspiracy includes the following:

[It was a part of the manner and means of the conspiracy that the defendants and others] at various times, concealed and caused others to conceal various material facts from IRBs that were responsible for supervising the clinical testing of devices at medical facilities where OP-1 was used, including, among others: that adverse events had been associated with the use of the mixture of OP-1 and Calstrux; that STRYKER BIOTECH employees were promoting a mixture of OP1 and Calstrux off-label to surgeons and surgical staff and were, in some instances, providing homemade recipes to physicians for mixing the OP-1 with Calstrux; and that surgeons were using OP-1 outside the HDE.

Superseding Indictment ¶58(e).

The concealment of material facts from the IRBs is a part of the case and the government is entitled to prove it through witness testimony. The government is merely seeking, as is its right, to prove the charges in the Indictment, including the one regarding concealment of facts from IRBs.

For all these reasons, this motion in limine should be denied.

Respectfully submitted,

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Dated: January 4, 2012

Certificate of Service

I hereby certify that the foregoing documents filed through the ECF system will be sent electronically to counsel for each defendant who is a registered participant as identified on the Notice of Electronic Filing (NEF).

/s/Jeremy M. Sternberg
Jeremy M. Sternberg
Assistant U.S. Attorney

Dated: January 4, 2012